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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,108

06/26/2006

Bo Rud Nielsen

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EXAMINER

ELLIS, SUEZU Y

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

04/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,108	Applicant(s) NIELSEN ET AL.	
	Examiner Suezu Ellis	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/6/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 6, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 19 is objected to because of the following informalities:

Claim 19 recites "The medical device according to a medical device comprising...". This appears redundant. Examiner suggests rewording to "A medical device comprising..." instead.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-17 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 11, it is unclear what applicant means by providing a polymer solution comprising the balance of a vehicle. It is unclear what a balance of a vehicle is. Please clarify.

Claims not specifically addressed are indefinite due to their dependency.

Claim 20 provides for the use of a polymer solution for the preparation of a cross-linked hydrophilic coating, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 20 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen (US 2002/0037943) in view of

With respect to claims 11, 17, 19 and 20, Madsen discloses in Examples 2 and 3, a method for the preparation of a cross-linked hydrophilic coating of a hydrophilic polymer on a substrate polymer surface of a medical device (catheter), said method comprising the steps of (i) providing a medical device comprising a substrate polymer having the substrate polymer surface, (ii) providing a polymer solution comprising 1-20% by weight of a hydrophilic polymer and 0-5% by weight of additive(s), (iii) applying said polymer solution to said substrate polymer surface, (iv) evaporating at least a part of the vehicle from said polymer solution present on said substrate polymer surface, and curing said hydrophilic polymer (Example 1). Madsen further discloses providing a plasticizer [0070], however fails to expressly disclose the polymer solution comprises a vehicle with plasticizing effect on the hydrophilic polymer, said vehicle comprising at least one plasticizer having a solubility in water of at least 6 g/L, a boiling point above 210°C at 760 mmHg, and a Hansen δ_H parameter of less than 20. However, it is well known in the art to coat a catheter with a polymer utilizing triethyl citrate as the plasticizer, as taught by Hunter et al. [0095], [0109]. Since applicant's example includes the same plasticizer, examiner interprets the triethyl citrate has the same properties as claimed. It would have been obvious to one of ordinary skill in the art to modify the type of plasticizer used in order to attain a coating with the desired properties (desired

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flexibility). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With respect to claim 12, the modified Madsen discloses the polymer solution is applied to said substrate polymer surface in one single application step (dipping) (Examples 2 and 3)

With respect to claim 13, the modified Madsen discloses the vehicle comprises at least one solvent (ethanol) (Examples 2 and 3).

With respect to claim 14, the modified Madsen discloses the polymer solution has the ranges claimed, with the exception of the content range of plasticizer. However, it would have been obvious to one of ordinary skill in the art to modify the desired range of the plasticizer depending on the desired properties (e.g. amount of flexibility of the coating). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 15, the modified Madsen discloses the substrate polymer is polyurethane (Example 2).

With respect to claims 16 and 21, the modified Madsen discloses the hydrophilic polymer is polyvinyl pyrrolidone (Examples 2 and 3).

With respect to claim 18, Madsen discloses a medical device comprising a hydrophilic coating of a cross-linked hydrophilic polymer, wherein the coating comprises a hydrophilic plasticizer ([0070], Examples 2 and 3). Madsen fails to expressly disclose

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the plasticizer has a solubility in water of at least 6 g/L, a boiling point above 210°C at 760 mmHg, and a Hansen δ_H parameter of less than 20. However, it is well known in the art to coat a catheter with a polymer utilizing triethyl citrate as the plasticizer, as taught by Hunter et al. [0095], [0109]. Since applicant's example includes the same plasticizer, examiner interprets the triethyl citrate has the same properties as claimed. It would have been obvious to one of ordinary skill in the art to modify the type of plasticizer used in order to attain a coating with the desired properties (desired flexibility). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615